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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/754,775	01/04/2001	David J. Grainger	295.009US3	6351

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EXAMINER

CRIARES, THEODORE J

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 11/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/754,775

Applicant(s)

GRAINGER ET AL.

Examiner

Theodore J. Criares

Art Unit

1617

-- Th MAILING DATE of this communication appears on the cover sheet with the corresponding address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 September 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 232 and 568 is/are pending in the application.
- 4a) Of the above claim(s) 158-172, 183, 184, 196-199, 204-206, 212-230 and 232 is/are withdrawn from consideration.

- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 173-182, 185-195, 200-203, 207-211 and 231 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

CLAIMS 158-232 ARE PRESENTED FOR
EXAMINATION

Applicant's election with traverse of Group II, claims 173-181 and 207-211 and 231, in Paper No. 13 is acknowledged. The Restriction Requirement of September 3, 2002 stated that claims 182-206 would be examined with the elected Group. However, after careful consideration of the elected Group, claims 173-182, 185-195, 200-203, 207-211 and 231 will be examined in this action. Claims 158-172, 183, 184, 196-199, 204-206, 212-230 and 232 will not be examined in this action since they read on a non-elected claims.

The traversal is on the ground(s) that 1) the claims are so closely related that they can not be separated; 2) that a burden is not placed on the Examiner and 3) that the claims can be searched in a single class. This is not found persuasive because a) the various medical disorders to be searched have acquired a separate status in the pharmaceutical art; b) an undue burden is placed on the examiner since the literature search would require a review of a vast number of medical journals and c) the subclasses to be searched in Class 514 relate to heterocyclic and non-heterocyclic compounds.

The requirement is still deemed proper.

REJECTION UNDER 35 USC § 112

Claims 173, 182, 207 and 232 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 173, 182, 207 and 232 recites the broad recitation R₃ is ethyl or chloroethyl, and these claims also recite "with the proviso that when R⁴, R⁵, and R⁶ are H, R³ is not ethyl" which is the narrower statement of the range/limitation.

There is no clear explanation in the specification what compounds fall within this definition.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 173-182, 185-195, 207-211 and 231 are rejected under 35 U.S.C. 102(a) as being anticipated by Grainger et al. (5,595,722).

Claims 173 –182, 185-195, 200-203 and 207-211 are drawn to a method for preventing or treating a cardiovascular or vascular indication characterized by a decreased lumen diameter by administering the compounds claimed in formula (I). Claims 200- 203 are drawn to increasing the level of TGF-beta and claim 231 is drawn to a method of arteriosclerosis.

Ganinger et al. teach at column 5, lines 60-66, and column 18, lines 34-48 the compounds which applicants are claiming in claims 173, 181 et seq. The cytotoxic amount is within the range set forth by applicants in the specification at page 32, line 21 to page 33, line 2. Applicants' compounds are taught by the reference to treat cardiovascular or vascular indicators characterized by a decreased lumen diameter at column 13 line 53 to column 14, lines 1-59. It is taught that applicants' compounds can be used to treat atherosclerosis and at column 22, line 51 to column 26, line 11 where it is taught that applicants' compounds can be used to in reducing lesion formations and decrease lumen to prevent and reduce atherosclerosis. See column 24 lines 11-24.

Claims 182-195 and 200-203 are rejected under 35 U.S.C. 102(a) as being anticipated by Grainger et al. (5,595,722).

Art Unit: 1617

Granger et al. teaches the use of the claimed active agents, in the amounts as claimed as evidenced in the citations stated above, that the claimed compounds are taught to increase the production of TGF-beta at column 13, lines 6-66.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-182, 185-195, 200-203, 207-211 and 231 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grainger et al. (5,595,722).

Grainger et al. teach all of the elements of applicants' claims. The difference between applicants' claims and the reference is applicants' definition of compounds has the phrase "with the proviso that when R⁴, R⁵, and R⁶ are H, R³ is not ethyl". However,

Art Unit: 1617

the compounds taught by the reference are those claimed by the applicants to have the same pharmaceutical activity. See claims 175, 177, 192, and 194.


The test of obviousness is "whether the teachings of the prior art, taken as a whole, would have made obvious the claimed invention." In re Gorman, 933 F.2d 982, 18 USPQ 2d 1885, (Fed. Cir. 1991). In view of the above rejection it is deemed that the evidence presented has established a prima facie case of obviousness. is presented.

None of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Theodore J. Criares whose telephone number is 308-4607. The examiner can normally be reached on 6:30 A.M. to 5:00P.M. Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-6897 for regular communications and N/A for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1235.


Theodore J. Criares
Primary Examiner
Art Unit 1617

Application/Control Number: 09/754,775

Page 7

Art Unit: 1617

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November 25, 2002